# **Complete Summary**

#### **GUIDELINE TITLE**

Depression.

## BIBLIOGRAPHIC SOURCE(S)

American Medical Directors Association (AMDA). Depression. Columbia (MD): American Medical Directors Association (AMDA); 2003. 36 p. [45 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: American Medical Directors Association (AMDA). Depression. Columbia (MD): American Medical Directors Association (AMDA); 1996. 20 p.

#### \*\* REGULATORY ALERT \*\*

# FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

 On May 12, 2006, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults.

A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant; however, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated. See the <u>FDA Web site</u> for more information.

• On July 1, 2005, in response to recent scientific publications that report the possibility of increased risk of suicidal behavior in adults treated with antidepressants, the U.S. Food and Drug Administration (FDA) issued a Public Health Advisory to update patients and healthcare providers with the latest information on this subject. Even before the publication of these recent reports, FDA had already begun the process of reviewing available data to determine whether there is an increased risk of suicidal behavior in adults taking antidepressants. The Agency has asked manufacturers to provide information from their trials using an approach similar to that used in the evaluation of the risk of suicidal behavior in the pediatric population taking antidepressants. This effort will involve hundreds of clinical trials and may take more than a year to complete. See the <u>FDA Web site</u> for more information.

# COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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# SCOPE

DISEASE/CONDITION(S)

Depression

**GUIDELINE CATEGORY** 

Diagnosis
Evaluation
Management
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice Geriatrics Internal Medicine Psychiatry Psychology

#### INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Nurses
Occupational Therapists
Pharmacists
Physical Therapists
Physician Assistants

**Physicians** 

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Speech-Language Pathologists

# GUI DELI NE OBJECTI VE(S)

- To improve the quality of care delivered to patients with depression in longterm care settings
- To guide care decisions and to define roles and responsibilities of appropriate care staff

#### TARGET POPULATION

Elderly residents of long-term care facilities with depression

#### INTERVENTIONS AND PRACTICES CONSIDERED

# Diagnosis/Assessment

- 1. Patient history
- 2. Depression screening tests (Geriatric Depression Scale [GDS], Cornell Scale for Depression in Dementia [CSDD], Center for Epidemiologic Studies of Depression Scale [CES-D], Patient Health Questionnaire 9 [PHQ 9])
- 3. Evaluation of patient for signs or symptoms of depression
- 4. Evaluation of patient for risk factors for depression
- 5. Monitoring of patient periodically for development of signs and symptoms of depression
- 6. Medical work-up as indicated for factors that may be contributing to signs and symptoms of possible depression
  - Chemistry profile (electrolytes, blood urea nitrogen, creatinine, glucose)
  - Complete blood count
  - Serum levels of anticonvulsant or tricyclics antidepressant, if taking either type of medication
  - Thyroid function (T3, T4, thyroid stimulating hormone [TSH])

- Other possible tests (electrocardiogram, folate level, serum calcium level, serum level of digoxin or theophylline if taking either medication, urinalysis, vitamin B 12 level)
- 7. Evaluation of patient for medications that might cause or contribute to depression
- 8. Adjusting or stopping problematic medications or indicating clearly why this is not feasible
- 9. Evaluation of patient for conditions that may increase the likelihood of depression or that may cause depressive symptoms; if present managing conditions
- 10. Evaluation of patient's response to treatment of comorbid condition(s)
- 11. Clarifying the diagnosis using Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) definitions and diagnostic tools (same as screening tools previously listed above)

# Management/Treatment

- 1. Consultative support with psychiatric specialist as indicated
- 2. Evaluation of potential for complications that may pose a risk to the patient or to others; if present, addressing complications
- 3. Individualized treatment for the patient's depression
  - Psychotherapy (cognitive-behavioral therapy, interpersonal therapy, problem-solving therapy, supportive therapy)
  - Medications (short-acting selective serotonin reuptake inhibitors [SSRIs] [paroxetine, sertraline, citalopram]; tricyclic antidepressants; bupropion; venlafaxine; methylphenidate; trazodone, nefazodone; mirtazapine)
  - Electroconvulsive therapy (ECT)
  - Psychosocial interventions (bereavement groups, family counseling, participation in social events, psychoeducation)
  - Combinations of above therapies
- 4. Monitoring of patient's response to treatment

# MAJOR OUTCOMES CONSIDERED

- Treatment response, recovery, remission, relapse, and recurrence
- Risk of relapse or recurrence of depression
- Safety of medications used to treat depression

#### METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

**Expert Consensus** 

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVI DENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Original guidelines are developed by interdisciplinary workgroups, using a process that combines evidence- and consensus-based approaches. The workgroups were comprised of practitioners and others involved in patient care in long-term care facilities. Beginning with a general guideline developed by an agency, association, or organization such as the Agency for Healthcare Research and Quality (AHRQ), pertinent articles and information, and a draft outline, the group worked to make a concise, usable guideline tailored to the long-term care setting. Because scientific research in the long-term care population is limited, many recommendations were based on the expert opinion of practitioners in the field.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

**COST ANALYSIS** 

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All American Medical Directors Association (AMDA) clinical practice guidelines undergo external review. The draft guideline is sent to approximately 175+ reviewers. These reviewers include AMDA physician members and independent physicians, specialists, and organizations that are knowledgeable of the guideline topic and the long-term care setting.

# RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The algorithm <u>Depression</u> is to be used in conjunction with the clinical practice guideline. The numbers next to the different components of the algorithm correspond with the steps in the text. Refer to the "Guideline Availability" field for information on obtaining the full text guideline.

# CLINICAL ALGORITHM(S)

An algorithm is provided for <u>Depression</u>.

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline was developed by an interdisciplinary work group using a process that combined evidence-and consensus-based thinking.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## POTENTIAL BENEFITS

This guideline recommends processes that, if followed, will help to ensure that depression among long-term care patients is adequately recognized, assessed, treated, and monitored.

## POTENTIAL HARMS

Adverse effects of antidepressant agents:

- Short-acting selective serotonin reuptake inhibitors (SSRIs) (paroxetine, sertraline, citalopram): insomnia, agitation, somnolence, decreased appetite, initial weight loss. Specific agents have potential for interaction with components of cytochrome system.
- Tricyclic antidepressants: dry mouth, blurred vision, constipation, urinary retention, inhibition of sweating, cognitive dysfunction
- Bupropion: seizures (in at-risk patients), little activity on serotonin or norepinephrine axes

- Venlafaxine: same as short-acting SSRIs; risk of blood pressure elevation at higher doses (>150–225 mg/day)
- Methylphenidate: anxiety, cardiac arrhythmia, insomnia, anorexia, weight loss, elevated blood pressure
- Trazodone, nefazodone (direct serotonin agents): sedation, postural hypotension (at high doses), priapism (rare)
- Mirtazapine: increased appetite, weight gain, sedation, somnolence, interaction with certain cytochrome pathways

# QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

- This clinical practice guideline is provided for discussion and educational purposes only and should not be used or in any way relied upon without consultation with and supervision of a qualified physician based on the case history and medical condition of a particular patient. The American Medical Directors Association (AMDA) and the American Health Care Association, their heirs, executors, administrators, successors, and assigns hereby disclaim any and all liability for damages of whatever kind resulting from the use, negligent or otherwise, of this clinical practice guideline.
- The utilization of the American Medical Director Association's Clinical Practice Guideline does not preclude compliance with State and Federal regulation as well as facility policies and procedures. They are not substitutes for the experience and judgment of clinicians and care-givers. The Clinical Practice Guidelines are not to be considered as standards of care but are developed to enhance the clinician's ability to practice.

# IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

The implementation of this clinical practice guideline (CPG) is outlined in four phases. Each phase presents a series of steps, which should be carried out in the process of implementing the practices presented in this guideline. Each phase is summarized below.

#### I. Recognition

• Define the area of improvement and determine if there is a CPG available for the defined area. Then evaluate the pertinence and feasibility of implementing the CPG.

#### II. Assessment

• Define the functions necessary for implementation and then educate and train staff. Assess and document performance and outcome indicators and then develop a system to measure outcomes.

# III. Implementation

- Identify and document how each step of the CPG will be carried out and develop an implementation timetable.
- Identify individual responsible for each step of the CPG.
- Identify support systems that impact the direct care.

• Educate and train appropriate individuals in specific CPG implementation and then implement the CPG.

## IV. Monitoring

- Evaluate performance based on relevant indicators and identify areas for improvement.
- Evaluate the predefined performance measures and obtain and provide feedback.

#### IMPLEMENTATION TOOLS

Clinical Algorithm
Personal Digital Assistant (PDA) Downloads
Tool Kits

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

# IDENTIFYING INFORMATION AND AVAILABILITY

## BIBLIOGRAPHIC SOURCE(S)

American Medical Directors Association (AMDA). Depression. Columbia (MD): American Medical Directors Association (AMDA); 2003. 36 p. [45 references]

## **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003

GUIDELINE DEVELOPER(S)

American Medical Directors Association - Professional Association

SOURCE(S) OF FUNDING

American Medical Directors Association

#### **GUIDELINE COMMITTEE**

Steering Committee

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: American Medical Directors Association (AMDA). Depression. Columbia (MD): American Medical Directors Association (AMDA); 1996. 20 p.

#### **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available from the American Medical Directors Association, 10480 Little Patuxent Pkwy, Suite 760, Columbia, MD 21044. Telephone: (800) 876-2632 or (410) 740-9743; Fax (410) 740-4572. Web site: <a href="https://www.amda.com">www.amda.com</a>.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guideline implementation: clinical practice guidelines. Columbia, MD: American Medical Directors Association, 1998, 28 p.
- We care: implementing clinical practice guidelines tool kit. Columbia, MD: American Medical Directors Association, 2003.

Electronic copies: None available

Print copies: Available from the American Medical Directors Association, 10480 Little Patuxent Pkwy, Suite 760, Columbia, MD 21044. Telephone: (800) 876-2632 or (410) 740-9743; Fax (410) 740-4572. Web site: <a href="https://www.amda.com">www.amda.com</a>.

The following is also available:

• PDA application: depression. Available in Palm/PDA and PocketPC formats from the American Medical Directors Association (AMDA) Web site.

#### PATIENT RESOURCES

None available

#### NGC STATUS

This NGC summary was completed by ECRI on July 6, 2004. The information was verified by the guideline developer on August 4, 2004. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration advisory on Paxil (paroxetine hydrochloride).

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